REMARKS

Claims 1, 4-22, 24, and 26-62 remain in the application. Claims 4, 9, 22, 28, 29, and 51 have been amended. Minor amendments have been made to the specification. A version with markings to show changes made follows page 12. Reconsideration of this application, as amended, is respectfully requested.

Claims 1, 4, 6, and 9 have been amended to specify that the indicator on the test strip select one of a multiplicity of testing functionalities of the measuring device. Support for these amendments can be found at page 8, lines 4-7 of the specification. Claims 22 and 28 have been amended to specify that the test port have at least two electrically conductive pins that interact with the indicator on the test strip to select one of a multiplicity of testing functionalities of the measuring device. Support for these amendments can be found at page 9, lines 19-26, at page 11, lines 15-23, and at page 15, lines 3-18 of the specification. Claims 29 and 51 have been amended to specify that the test port have at least one indentation or hole that interacts with the indicator on the test strip to select one of a multiplicity of testing functionalities of the measuring device. Support for these amendments can be found at page 9, lines 19-26, at page 11, lines 15-23, and at page 15, lines 3-18 of the specification.

The specification has been amended in some locations to conform to the claims.

Claims 1-3, 9, 10, 12-18, 21-24, 27, and 28 stand rejected under 35 U. S. C. § 102 (b) as being anticipated by US Patent 5,580,794 to Allen. This rejection is respectfully traversed for the following reasons.

Allen, U. S. Patent No. 5,580,794 (hereinafter "Allen"), discloses a disposable electronic assay device comprising card-like housing containing a sample receptor means for receiving a sample of body fluid containing an analyte to be determined, a sample treatment means for reaction with sample fluid components to yield a physically detectable change which correlates with the amount of analyte in the sample, a detector means responsive to the physically detectable change for producing an electrical signal which

correlates with the amount of analyte in the sample, signal processing means connected to the detector means for converting the electrical signal to a digital test result output, and visually readable output means connected to the signal processor means for receiving and presenting the test result output.

The present invention provides products wherein a user may perform a multiplicity of different assays with a single measuring device having a multiplicity of testing functionalities, without the need for manually reconfiguring or switching between different functionalities of the device. By eliminating the need for the user to manually set the device when changing from one testing functionality to another, the invention provides increased convenience and speed of use, and reduces the likelihood of human error. The invention employs a test port that is capable of recognizing various diagnostic test strips having different testing functionalities, e.g., glucose, ketone bodies. Each type of diagnostic test strip comprises a different indicator (or indicators) that enables the test port to differentiate one type of diagnostic test strip from another type of diagnostic test strip. When the user inserts a diagnostic test strip into the test port of the measuring device, the test port will identify the appropriate functionality of the measuring device and automatically reconfigure or switch the measuring device to the appropriate functionality. See page 7, lines 3-17 of the specification. Specific types of indicators are described at page 9, line 27 through page 11, line 7 of the specification. Test ports for interacting with the diagnostic test strips are described at page 11, line 9 through page 12, line 20 of the specification. Neither of the references relied on by the Examiner disclose or suggest the test strips or the test ports of the type claimed in this application.

At column 6, lines 48-52 of Allen, it is stated:

> Single or multiple assays can be done at one time. For example, a single assay can be done measuring cholesterol or one device can be set up to measure both total and HDL cholesterol from a single sample. One test device can be set up to measure one, two, three, or more analytes **at one tim** . (emphasis added)

This statement does not disclose or suggest an indicator on a test strip that can allow a measuring device to differentiate between two or more types of test strips (e.g., glucose, ketone bodies) to select one (e.g., glucose) of a multiplicity of testing functionalities of the measuring device. This statement does not disclose or suggest a test port (of a measuring device) having a sensor that can select one (e.g., glucose) of a multiplicity of testing functionalities of the measuring device. This statement does not disclose or suggest that that the measuring device and the test strips described in Allen can cooperate to differentiate between two or more types of assays, but must perform all of the assays on a test strip at the same time. In Example 1 of Allen, it is shown that more than one assay on the test strip can be carried out at the same time. However, the test strip and the test port in Allen cannot communicate to select a particular assay from a multiplicity of assays to be performed at a particular time. In Allen, all of the assays in a given set of assays must be carried out at the same time. In view of the foregoing, it is submitted that Allen does not anticipate any claim of this application. It should be noted that claims 1, 4, 6, 9, 22, 28, 29, and 51 have been amended to change the phrase " thereby selecting at least one of said multiplicity of testing functionalities of said measuring device" to "to thereby select one of said multiplicity of testing functionalities of said measuring device."

Claims 1-8, 10-22, 24, 26, and 28-62 were rejected under 35 U. S. C. § 102 (b) as being anticipated by US Patent 5,312, 590 to Gunasingham. This rejection is respectfully traversed for the following reasons.

Gunasingham, U. S. Patent No: 5,312,590 (hereinafter "Gunasingham"), discloses a method and apparatus for measuring a wide range of chemical species in liquids. The apparatus employs a flat test device comprising a number of symmetrically arranged sensor elements that enable the multi-species determination from a single sample drop. Each sensor element is coated with a unique reaction layer that makes it responsive to specific chemical species. Additionally, all the sensor elements are coated with a single membrane which serves the dual function of a diffusion barrier and filter. An insulating layer is further coated over the membrane with specific provision for wells where the sample and reference solutions may be placed. In a preferred embodiment of the invention, the sample well is

centrally located so that chemical species present in the sample can diffuse equally to the various sensing elements. The reference solution wells are located adjacent to the specific sensing element. The center of the sample solution well and the center of the reference solution well are equidistant to the respective sensing element so that the diffusion of chemical species from the sample and reference solutions occurs equally.

As stated previously, each type of diagnostic test strip claimed in the present application comprises a different indicator (or indicators) that enables the test port to differentiate one type of diagnostic test strip from another type of diagnostic test strip. When the user inserts a diagnostic test strip into the test port of the measuring device, the test port will identify the appropriate functionality of the measuring device and automatically reconfigure or switch the measuring device to the appropriate functionality.

At column 8, lines 24-44 of Gunasingham, multi-species detection was described as follows:

> The device consists of four symmetrically arranged sensor elements (16) that enable multi-species determination from a single sample drop. Each sensor element is coated with a unique reaction layer (17) that makes it responsive to specific chemical species. Additionally, all the sensor elements are coated with a single membrane (18) which serves the dual function of a diffusion barrier and filter. An insulating layer (19) is further coated over the membrane with specific provision for wells where the sample (20) and reference solutions (21) may be placed. The sample well is centrally located so that chemical species present in the sample can diffuse equally to the various sensing elements. The reference solution wells are located adjacent to the specific sensing element. The center of the sample solution well and the center of the reference solution well are equidistant to the respective sensing element so that **th diffusi n of chemical sp ci s from the sampl and r f r nce solutions occurs qually**. (emphasis added)

This statement does not disclose or suggest an indicator on a test strip that can allow a measuring device to differentiate between two or more types of test strips (e.g., glucose, ketone bodies) to select one (e.g., glucose) of a multiplicity of testing functionalities of the measuring device. This statement does not disclose or suggest a test port (of a measuring device) having a sensor that can select one (e.g., glucose) of a multiplicity of testing functionalities of the measuring device. This statement does not disclose or suggest that the measuring device and the test strips described in Gunasingham can cooperate to differentiate between two or more types of assays, but must perform all of the assays on a test strip at the same time. In Example 4 of Gunasingham, it is shown that more than one assay can be carried out at the same time. However, the test strip and the test port in Gunasingham cannot communicate to select a particular assay from a plurality of assays to be performed at a particular time. In Gunasingham, all of the assays in a given set of assays must be carried out at the same time. In view of the foregoing, it is submitted that Gunasingham does not anticipate any claim of this application. It should be noted that claims 1, 4, 6, 9, 22, 28, 29, and 51 have been amended to change the phrase " thereby selecting at least one of said multiplicity of testing functionalities of said measuring device" to "to thereby select one of said multiplicity of testing functionalities of said measuring device."

In view of the foregoing, it is submitted that claims 1, 4-22, 24, and 26-62, as amended, are in condition for allowance, and official Notice of Allowance is respectfully requested.

Respectfully submitted,
M.E. Lewis, et al.

23492

ABBOTT LABORATORIES
Telephone: (847) 937-6182
Facsimile: (847) 938-2623

David L. Weinstein
Registration No. 28,128
Attorney for Applicants

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Please replace the paragraphs beginning at page 3, line 1 and ending at page 5, line 6 with the following:

SUMMARY OF THE INVENTION

The invention provides a multichemistry measuring apparatus and diagnostic test strips which, in combination with the multichemistry measuring apparatus, provide a multichemistry diagnostic testing system. In one aspect, the invention relates to diagnostic test strips for chemical analysis of a sample. The diagnostic test strips are adapted for use in combination with a measuring apparatus having a test port. The apparatus is capable of performing a multiplicity of testing functionalities. In this aspect, the test strip comprises a support capable of releasably engaging the test port; at least one reaction area on the support for receiving the sample; and an indicator capable of interacting with the test port to select [at least] one of the multiplicity of testing functionalities of the measuring apparatus. In one embodiment, the indicator comprises one or more electrically conductive contacts capable of engaging at least two electrically conductive pins within the test port. In such an embodiment, the electrically conductive contacts close at least one circuit between the at least two electrically conductive pins within the test port. In preferred embodiments, the electrically conductive contacts comprise a material selected from: carbon, gold, silver, platinum, nickel, palladium, titanium, copper, or lead. In preferred embodiments, the electrically conductive contacts comprise an electrically conductive printable ink. In another embodiment, the indicator comprises one or more projections or depressions capable of mechanically engaging one or more pins within the test port. In such an embodiment, the mechanical displacement of at least one of the pins results in the opening or closing of at least one circuit. In another embodiment, the indicator comprises an optically detectable pattern

capable of signaling to or being detected by an optical detector in the test port. In preferred embodiments, the optically detectable indicator comprises a pattern formed by a printable ink.

In another aspect, the present invention provides a test port for use in a measuring apparatus that is capable of performing a multiplicity of testing functionalities and is adapted for use in combination with a multiplicity of different types of diagnostic test strips. Each type of test strip corresponds to at least one of the testing functionalities of the apparatus, and at least some types of test strips have indicators of the testing functionality on them. In this aspect, the test port comprises a sensor capable of specifically interacting with the indicator(s) on the test strips, thereby selecting [at least] one of the multiplicity of testing functionalities corresponding to the type of test strip. In one embodiment, the indicators on the test strips are electrically conductive, and the sensor of the test port comprises a multiplicity of electrically conductive pins. In such an embodiment, at least two of the pins can be bridged by an indicator, thereby closing an electrical circuit. In another embodiment, the indicators on the test strips comprise projections or depressions, and the sensor of the port is a pin that may be physically displaced by or into the indicators, thereby opening or closing an electrical circuit. In another embodiment, the indicators comprise an optically detectable pattern, and the sensor of the port is an optical sensor.

In another aspect, the invention provides a measuring apparatus having a multiplicity of testing functionalities for chemical analysis. The apparatus is adapted for use in combination with a multiplicity of different types of test strips. Each of the types of test strips corresponds to at least one of the testing functionalities, and at least some of the types of test strips have indicators of the testing functionality on them. The apparatus includes: a test port including a sensor capable of interacting with the indicators on the test strips to select [at least] one of the multiplicity of testing functionalities; and a multiplicity of test circuitries for specifically measuring reactions on the test strips, the reactions corresponding to the multiplicity of testing functionalities.

IN THE CLAIMS

Kindly rewrite claims 4, 9, 22, 28, 29, and 51 as follows:

1. (Twice amended) A test strip for chemical analysis of a sample, adapted for use in combination with a measuring device having a test port and capable of performing a multiplicity of testing functionalities, said test strip comprising:

(a) a support capable of releasably engaging said test port;

(b) at least one reaction area on said support for receiving said sample; and

(c) an indicator capable of interacting with said test port to select [at least] one of said multiplicity of testing functionalities of said measuring device, wherein said indicator comprises at least one electrically conductive indicator contact capable of engaging at least two electrically conductive pins within said test port [,] to thereby [selecting at least] select one of said multiplicity of testing functionalities of said measuring device.

4. (Twice amended) A test strip for chemical analysis of a sample, adapted for use in combination with a measuring device having a test port and capable of performing a multiplicity of testing functionalities, said test strip comprising:

(a) a support capable of releasably engaging said test port;

(b) at least one reaction area on said support for receiving said sample; and

(c) an indicator capable of interacting with said test port to select [at least] one of said multiplicity of testing functionalities of said measuring device, wherein said indicator comprises at least one projection on said support, said at least one projection capable of mechanically engaging at least one pin within said test port [,] to thereby [selecting at least] select one of said multiplicity of testing functionalities of said measuring device.

6. (Twice amended) A test strip for chemical analysis of a sample, adapted for use in combination with a measuring device having a test port and capable of performing a multiplicity of testing functionalities, said test strip comprising:

(a) a support capable of releasably engaging said test port;

(b) at least one reaction area on said support for receiving said sample; and

(c) an indicator capable of interacting with said test port to select [at least] one of said multiplicity of testing functionalities of said measuring device, wherein said indicator comprises at least one depression on said support, said at least one depression capable of mechanically engaging at least one pin within said test port [,] to thereby [selecting at least] select one of said multiplicity of testing functionalities of said measuring device.

9. (Twice amended) A test strip for chemical analysis of a sample, adapted for use in combination with a measuring device having a test port and capable of performing a multiplicity of testing functionalities, said test strip comprising:

(a) a support capable of releasably engaging said test port;

(b) at least one reaction area on said support for receiving said sample; and

(c) an indicator capable of interacting with said test port to select [at least] one of said multiplicity of testing functionalities of said measuring device, wherein said indicator comprises an optically detectable pattern capable of signaling or being detected by an optical detector in said test port [,] to thereby [selecting at least] select one of said multiplicity of testing functionalities of said measuring device.

22. (Twice amended) A test port for use in a measuring device capable of performing a multiplicity of testing functionalities and adapted for use with the test strip of claim 1, said test port comprising at least two electrically conductive pins, said at least two electrically conductive pins capable of specifically interacting with said at least one electrically conductive

indicator contact on said test strip [,] to thereby [selecting at least] select one of said multiplicity of testing functionalities of said measuring device.

28. (Twice amended) A measuring device having a multiplicity of testing functionalities for chemical analysis, adapted for use with the test strip of claim 1, said device comprising:

(a) a test port comprising at least two electrically conductive pins, said at least two electrically conductive pins capable of specifically interacting with said at least one electrically conductive indicator contact on said test strip [,] to thereby [selecting at least] select one of said multiplicity of testing functionalities of said measuring device; and

(b) a multiplicity of test circuitries for specifically measuring reactions on said test strip, said multiplicity of said test circuitries corresponding to said multiplicity of testing functionalities.

29. (Once amended) A test port for use in a measuring device capable of performing a multiplicity of testing functionalities and adapted for use with the test strip of claim 6, wherein said test port comprises a pattern of at least one indentation or hole, wherein said at least one indentation or hole fails to displace at least one pin of said test strip upon insertion of said test strip into said test port [,] to thereby [selecting at least] select one of said multiplicity of testing functionalities of said measuring device.

51. (Once amended) A measuring device having a multiplicity of testing functionalities for chemical analysis, adapted for use with the test strip of claim 6, said device comprising:

(a) a test port comprising a pattern of at least one indentation or hole, wherein said at least one indentation or hole fails to displace at least one pin of said test strip upon insertion of said test strip into said test port [,] to thereby [selecting at least] select one of said multiplicity of testing functionalities of said measuring device; and

(b) a multiplicity of test circuitries for specifically measuring reactions on said test strip, said multiplicity of said test circuitries corresponding to said multiplicity of testing functionalities.